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EXAMINER	
BARTON, JEFFREY THOMAS	
ART UNIT	PAPER NUMBER
1753	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/061,001	STAATS, SAU LAN TANG	
	Examiner	Art Unit	
	Jeffrey T Barton	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 April 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20040707*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. "Injection-molded Microfluidic Devices" is suggested as an alternative.

3. The disclosure is objected to because of the following informalities: on page 21, line 19, Figure 9C is referenced, although there is no figure 9C among the drawings.

Appropriate correction is required.

4. Claim 9 is objected to because of the use of "comprising" in line 2 when "comprises" appears to have been intended. Appropriate correction is required.

5. Claims 28 and 29 are objected to because of improper antecedent basis. No polymeric material was explicitly required in claim 1, and thus:

a. For claim 28, in line 2 before "polymeric material", "the" should be deleted and "a" inserted in its place.

b. For claim 29, in the following treatment, "the polymeric material" is presumed to be referring to "injection moldable material" as recited in claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The production of a cover for the device by

injection molding (Claims 1 and 37, lines 1-5), as recited in these amended claims, is not supported by the specification. The specification describes the production of the substrate by injection molding (Pages 26-31), but does not describe injection molding of the cover of the device.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Regarding claims 1 and 37, in the following treatment, weight is not given to the limitation, "an injection molded article", because the claim is drawn to a product (microfluidic device) produced by a process (injection molding). "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP § 2113.

Even in the case that the limitation to injection molding was found to be material to patentability, devices such as those described in the instant application and the prior art cited have been manufactured by injection molding previously. See Parce et al. (US 5,942,443)

10. Claims 1-3, 8, 17,18, 20, 25, 26, 28, 31, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Zanzucchi et al.

Addressing claims 1 and 2, Zanzucchi et al disclose a microfluidic device (Figure 6A) comprising: a substrate (310) with a top surface comprising a channel (222), wherein the channel has a width, a bottom, and a sidewall (Figures 6A and 7); a cover (300) positioned over the substrate in alignment with the substrate (Figure 6A, edges and features aligned); wherein the channel is accessed through an access port to the channel, the access port positioned on at least one of the cover and the bottom. (vertical channel 225, access through channel bottom); and wherein the device is formed of an injection-moldable material (Column 26, lines 10-16).

Addressing claim 3, Zanzucchi et al disclose a microfluidic device (Figure 6B) wherein the access port to the channel (212) is an opening on the cover. (302, access to channel 212 via reservoir 200)

Addressing claim 8, Zanzucchi et al disclose a microfluidic device (Figure 6A) wherein the channel bottom (bottom of 222) is beneath the plane of the top surface of the substrate (310).

Addressing claim 17, Zanzucchi et al disclose a microfluidic device (Figure 9) comprising a first and second channel (400A and 440), the second channel (440) being positioned below the first channel (400A), and with the first channel having a conduit (410A) extending from the bottom of the first channel to the second channel.

Addressing claim 18, Zanzucchi et al disclose a microfluidic device (Figure 9), wherein the device further comprises a microreactor (350) connected to the channels by a capillary (442).

Addressing claim 20, Zanzucchi et al disclose a microfluidic device (Figure 6A), wherein the cover comprises an interconnecting duct (363), with the duct connecting two channels via access ports (390 and 218, interface between duct and channel is an access port).

Addressing claim 25, Zanzucchi et al disclose a microfluidic device (Figure 9) wherein the channel comprises a first linear section (400A) and a second linear section (430), wherein the two sections are perpendicular.

Addressing claim 26, Zanzucchi et al disclose a microfluidic device wherein the channel bottom has a width of greater than 100 micrometers. (Column 28, lines 44-48)

Addressing claim 28, Zanzucchi et al disclose a microfluidic device wherein the sidewall and channel bottom are formed from a polymeric material. (Column 26, lines 7-16)

Addressing claim 31, Zanzucchi et al disclose a microfluidic device (Figure 6A) comprising an additional substrate (320) with a channel architecture (350, 355), wherein the substrates are bonded together (Column 8, lines 28-32), and wherein the device

comprises a conduit (390) connecting the channel (363, 218, etc.) and the channel architecture (350, 355)

Addressing claim 37, Zanzucchi et al disclose a microfluidic device (Figure 7, 6A) comprising a substrate (310) with a top surface comprising a plurality of non-intersecting channels (222A1-D1, 222A2-D2), wherein each channel has a width a bottom and a sidewall; and a cover (300) positioned over and aligned with the substrate, wherein each of the channels are accessed through an access port to the channel, the access port being positioned on at least one of the cover and the bottom (channel 225, access through bottom of channel 222)

11. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuchs et al.

Addressing claim 1, Fuchs discloses a microfluidic device (Figure 2) comprising: a substrate (22) with a top surface comprising a channel (14), wherein the channel has a width, a bottom, and a sidewall (See also Figure 4); a cover (20) positioned over the substrate in alignment with the substrate (Figure 4, edges and features aligned); wherein the channel is accessed through an access port to the channel, the access port positioned on at least one of the cover and the bottom. (port 24, through cover); and wherein the device is formed of an injection moldable material (Column 4, lines 62-65; Column 12, lines 45-47)

Addressing claim 4, Fuchs et al disclose a microfluidic device (Figure 2) wherein the channel bottom (channel 14) is coplanar with the top surface of the substrate (22),

and the channel sidewall rises from the substrate surface at an angle between 45 and 135 degrees (approximately 90 degrees, Figures 2 and 4), and wherein the substrate and the sidewall are composed of a polymeric material. (Column 4, lines 62-65; Column 12, lines 45-47)

12. Claims 1 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Sundberg et al.

Addressing claim 1, Sundberg et al disclose a microfluidic device (Figure 6) comprising: a substrate (16) with a top surface comprising a channel (18), wherein the channel has a width, a bottom, and a sidewall (Figures 6,7 - rectangular cross-section); a cover (12) with an access port (64) positioned over the substrate in alignment with the substrate; and wherein the device is formed of an injection moldable material (Column 6, line 57; Column 7, line 6)

Addressing claim 24, Sundberg et al disclose a microfluidic device (Figures 7 and 8) that comprises a channel structure (90) positioned within the channel (78) and oriented perpendicular to both the channel sidewall and bottom.

13. Claims 1, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Parce et al (US 5,942,443).

Addressing claim 1, Parce et al disclose a microfluidic device (Figure 1) comprising: a substrate (102) with a top surface comprising a channel (e.g. 110), wherein the channel has a width, a bottom, and a sidewall (Figure 1 shows width, any

anisotropic etch or printing method will give distinct sidewalls and bottom; Column 8, line 58 - Column 9, line 7); a cover with access port positioned over the substrate in alignment with the substrate (Column 9, lines 8-18); and wherein the device is formed of an injection moldable material. (Column 8, lines 38-42; Column 8, line 58 - Column 9, line 7)

Addressing claim 29, Parce et al disclose the construction of their microfluidic devices using low-melt viscosity polymer. (Column 8, lines 38-42)

Addressing claim 30, Parce et al disclose the construction of their microfluidic devices using polystyrene or polycarbonate. (Column 8, lines 38-42)

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Witt et al in view of Fuchs et al.

Witt et al disclose a microfluidic device (Figure 10) comprising a substrate (104) with a top surface comprising a channel (110) that has width, a bottom, and a sidewall (Figure 13), a cover (112) with an access port (122) to the channel positioned over and aligned with the substrate, wherein the device is formed of an injection moldable,

polymeric material. (Column 17, lines 9-12) This device (Figure 1) also includes a plurality of thin sidewall regions (Walls 10a and 10b, regions adjacent to antennas 12 and 13), wherein metal is deposited on the thinned regions (Antennas comprise sputtered copper, Column 13, lines 9-14)

Witt et al do not explicitly disclose a microfluidic device wherein the channel bottom is coplanar with the top surface of the substrate, and the sidewalls rise from the substrate surface at an angle between 45 and 135 degrees.

Fuchs et al disclose a microfluidic device described above in the treatment of claim 4, which comprises a microchannel, the bottom of which is coplanar with the substrate and with sidewalls that rise approximately 90 degrees to the substrate.

Fuchs et al and Witt et al are analogous art in that both describe microfluidic devices.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Witt et al by constructing it such that the microchannel bottom is coplanar with the substrate, with perpendicular sidewalls defined by a separately-prepared second layer, as taught by Fuchs et al, because it would simplify prevention of copper deposition in the microchannel.

16. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al in view of Kennedy (US 5,876,675).

Zanzucchi et al disclose a device as described above in the treatment of claim 1.

Zanzucchi et al do not explicitly disclose a device further comprising a device adapted to align the cover with the substrate (Claim 9), where the device is a dowel pin on the substrate (Claim 10), or where the device is a protrusion on the cover. (Claim 11)

Kennedy discloses alignment structures including pins with corresponding holes, or bevels, ridges, notches or tabs serving the same purpose (Column 10, lines 1-25)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Zanzucchi et al by adding pins or other protrusions with corresponding recesses to complementary positions on the substrate and cover, as taught by Kennedy, because it would simplify proper preparation of the device. It would also be obvious to place pins or holes on either plate, as it is a matter of manufacturing choice, with no significant functional difference between options.

17. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al and Kennedy (US 5,876,675) as applied to claim 9 above, and further in view of Wu et al.

Zanzucchi et al and Kennedy disclose a combination as described above in the treatment of claim 9.

Neither Zanzucchi et al nor Kennedy explicitly disclose a device further comprising a device adapted to align the cover with the substrate (Claim 9) with accuracy better than 0.001 inch.

Wu et al disclose a means of aligning plates with accuracy better than 25 microns (0.001 inch). (Column 27, lines 19-20)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination of Zanzucchi et al and Kennedy by providing an alignment mechanism with accuracy better than 0.001 inch, as taught by Wu et al, because it would allow for smaller reservoirs and less wasted sample material.

18. Claims 1, 13, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al in view of Parce et al (US 5,942,443).

Relevant to claim 1, Kovacs et al disclose a microfluidic device (Figure 8) comprising a substrate (12) with a top surface comprising a channel (20) that has width, a bottom, and a sidewall (Figure 12, channel 20), a cover (10) with an access port (16) to the channel positioned over and aligned with the substrate.

Relevant to claim 13, Kovacs et al disclose this device (Figure 8) further comprising a capillary (14) positioned in the channel access port (16) and inserted in the channel, wherein the access port diameter and the outer diameter of the capillary are approximately equal. (Figure 8, D1)

Relevant to claim 14, Kovacs et al further disclose the use of an adhesive to secure the outer circumference of the capillary to the access port. (Column 5, lines 26-32)

Relevant to claim 16, Kovacs et al disclose the device further comprising a capillary (14) positioned in the channel access port and inserted in the channel (Figure 8), wherein the capillary inner cross-sectional area and the channel cross-sectional area

are approximately equal. (Figure 8, D2; Column 5, lines 59-65; Figure 1 shows alternative, conventional channel shapes)

Kovacs et al do not explicitly disclose a microfluidic device that is formed from an injection moldable material.

Parce et al disclose the manufacture of microfluidic devices of similar design to that of Kovacs et al (i.e. top plate with access port, bottom plate with channels) using injection moldable material. (Column 8, line 10 - Column 9, line 18)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kovacs et al by manufacturing the plates 10 and 12 from an injection moldable material, as taught by Parce et al, because it could lower costs of manufacture and result in a more rugged device.

19. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al and Parce et al (US 5,942,443) as applied to claim 13 above, and further in view of Shartle et al.

Kovacs et al and Parce et al disclose a combination as described above in addressing claim 13.

Neither Kovacs et al nor Parce et al explicitly disclose the use of a transparent polymeric capillary in their devices.

Shartle et al disclose the use of transparent polymeric capillaries in an electrophoresis apparatus. (Column 4, lines 48-51)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination of Kovacs et al and Parce et al by replacing the capillary with a transparent polymeric capillary, as taught by Shartle et al, because it could be flexible and easy to manipulate, and also reduce costs.

20. Claims 1 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knapp et al in view of Bjornson et al.

Relevant to claim 1, Knapp et al disclose a microfluidic device (Figure 13) comprising a substrate (1335) with a top surface comprising a channel (e.g. 1345) that has width, a bottom, and a sidewall (Figure 13 shows width, any anisotropic etch method or printing method will give distinct sidewalls and bottom; Column 42, lines 36-67), a cover with an access port to the channel positioned over and aligned with the substrate (Column 43, lines 1-12), wherein the device is formed of an injection moldable material (Column 41, lines 58-62; Column 42, lines 47-53)

Relevant to claim 19, Knapp et al disclose devices wherein the substrate further comprises a nozzle used for ingress or egress of fluids (Column 56, lines 6-9) in fluid communication with the microfluidic channels. (Figures 13-18)

Knapp et al do not explicitly disclose a device wherein the substrate comprises a plurality of conical nozzles positioned in a geometrical array.

Bjornson et al disclose a device for dispensing fluids comprising a substrate with a geometrical array of conical nozzles. (Figures 1, 2C)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Knapp et al by providing multiple conical nozzles in a geometric array, a nozzle corresponding to each channel system, as taught by Bjornson et al, because it could provide efficient, high-throughput analysis of samples in a standard multiwell plate.

21. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al (US 5,942,443) in view of Jedrzejewski et al.

Parce et al disclose a device as described above in addressing claim 1.

Parce et al do not explicitly disclose a device wherein the cover comprises a protrusion adjacent to the inner surface of the sidewall (Claim 21), a device wherein the cover comprises a protrusion adjacent to the outer surface of the sidewall (Claim 22), or a device wherein the cover comprises a protrusion adjacent to the outer surface of the sidewall and an interstitial volume is formed between the substrate and the cover. (Claim 23).

Relevant to claims 21-23, Jedrzejewski et al disclose a similar microfluidic device (Figure 6l), which comprises a cover (291) and substrate (290) with sidewalls (hollow protrusions from 290) comprising an inner surface facing the channel and an outer surface opposite the inner surface, the cover comprising a bottom surface facing the top surface of the substrate, and the cover further comprising a protrusion extending from its bottom surface, wherein the protrusion is adjacent the outer surface of the sidewall,

and an interstitial volume between the cover and substrate is formed. (Above hollow protrusions from 290)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Parce et al by using protrusions from the cover to guide the alignment of the cover and substrate, as taught by Jedrzejewski et al, because it would simplify device assembly. It would also have been obvious to provide protrusions from the cover adjacent to the inner surface of the sidewall, because it is a matter of design choice with no apparent distinction in function.

22. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al in view of Witt et al.

Zanzucchi et al disclose a microfluidic device as described above for claim 1. The channel sidewall height is disclosed as preferably 50-80 microns. (Column 28, lines 40-44)

Zanzucchi et al do not explicitly disclose channel sidewalls from 10-50 microns in height.

Witt et al disclose microfluidic channels with sidewalls of 25 microns. (Column 20, line 53)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Zanzucchi et al by reducing the sidewall height to 25 microns, as taught by Witt et al, because it would allow the manipulation of smaller sample volumes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
July 14, 2004

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